

The opinion in support of the decision being
entered today is not binding precedent of the Board.

Paper **44**

By: Trial Section Merits Panel
Board of Patent Appeals and Interferences
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Filed:
18 May 2004

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

QING WANG, MITCHELL H. FINER
and XIAO-CHI JIA

Junior Party,
Application 08/333,680

v.

JEAN-LUC IMLER, MAJID MEHTALI
and ANDREA PAVIRANI

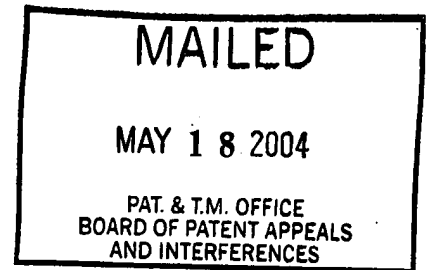
Senior Party
Application 09/218,143
Application 09/739,007

Patent Interference No. 105,136

Before: TORCZON, SPIEGEL, and LANE Administrative Patent Judges.

LANE, Administrative Patent Judge.

Judgment-Rule 658 and Rule 659



I. Introduction

Wang did not file its case-in-chief on priority within the time set by the Administrative Patent Judge ("APJ"). Wang has filed a preliminary motion attacking the patentability of certain Imler involved claims, but those claims have been cancelled by Imler. There being no further issues for the panel to resolve, judgment is entered against Wang on the issue of priority and against Imler as to the claims it has cancelled.

II. Background

The interference was declared on 16 July 2003 between junior party QING WANG, MITCHELL H. FINER and XIAO-CHI JIA ("Wang") and senior party JEAN-LUC IMLER, MAJID MEHTALI and ANDREA PAVIRANI ("Imler").

As stated by Imler (Paper 38, at 4, emphasis in original):

...the present interference was declared, for procedural and administrative purposes, after a complete preliminary motions phase in the '821^[1] interference, when, as a result of the decisions on motions in the '821 interference, the Board held it appropriate to add Imler's claims 66 and 67 to the Imler '143 application. See Order at 3. The present interference was originally declared with claims 66 and 67 of the Imler '143 application. Paper 1 (Notice Declaring Interference) at 4. Claims 66 and 67, as added to the Imler '143 application, define two of the four alternatives of the count (the other two alternatives being directed to Wang's claims). See Paper 1, at 4. The present interference was subsequently redeclared so as to add certain claims of the Imler '007 application as being designated to correspond to the count. Paper 14, at 8. The count was not modified as a result of the addition of these claims from the Imler '007 application.

¹ Interference 104,821, which was declared on 8 March 2002. An order awarding judgment on priority against Imler was entered in the '821 interference on 16 July 2003 ('821, Paper 116 at 42).

Because it was determined that a preliminary motion period for interference 105,136 was de facto provided in the '821 interference as to the involved Wang claims and Imler's involved 09/218,143 ("143") claims, the APJ did not authorize Wang to file a preliminary motion under 37 CFR § 1.633(a) attacking the patentability of the '143 claims. However, Wang was authorized to file a preliminary motion under 37 CFR § 1.633(a) attacking the patentability of the corresponding claims of Imler's 09/739,007("007") application since these claims were not involved in the '821 interference. Imler was not given an opportunity to file a 37 CFR § 1.633(i) motion but was authorized to seek patentable claims before the examiner.

While Wang filed Wang preliminary motion 1 attacking Imler's '007 involved claims, Wang filed no case-in-chief on priority. Imler filed its miscellaneous motion 1 seeking immediate judgment against Wang and termination of the interference without a decision on Wang preliminary motion 1. Subsequently Imler was authorized to file an amendment cancelling all of its '007 claims that correspond to the count. Accordingly, Wang preliminary motion 1, and Imler miscellaneous motion 1 with respect to Wang preliminary motion 1, are moot.

III. Findings of fact

The record supports the following findings of fact and any other findings of fact set forth in this decision by at least a preponderance of the evidence.

The parties

1. Wang is involved in the interference on the basis of its 08/333,680 application filed 3 November 1994 (Paper 14 at 6).
2. According to Wang, its real party in interest is Cell Genesys, Inc. (Paper 8 at 2).
3. Imler is involved in the interference on the basis of its '143 application filed 22 December 1988 and its '007 application filed 19 December 2000 (Paper 14 at 6-7).
4. According to Imler, its real party in interest is Transgene, S.A. (Paper 6 at 2).

The count

5. Count 1 of the interference is as follows (Paper 1 at 4 and Paper 14 at 8):²

The recombinant adenoviral vector of claim 46 of Wang
08/333,680, wherein the two gene regions are E1 and E4

or

The recombinant adenoviral vector of claim 38 or 47 of Wang
08/333, 680

or

The recombinant adenovirus of claim 66 of Imler 09/218,143

or

The recombinant adenoviral vector of claim 67 or Imler 09/218,143.

² The interference was redeclared to add the '007 application to the interference (Paper 14). Count 1 was not modified in the redeclaration.

6. Wang claims 37, 38, 46, 47, 52, 54, and 56 were designated as corresponding to Count 1 (Paper 14 at 8).
7. Imler '143 claims 66 and 67 were designated as corresponding to Count 1 (Paper 14 at 8).
8. Imler '007 claims 73-77, 80-88, 91, and 92 were designated as corresponding to Count 1 (Paper 14 at 8).

The '821 interference

9. During the preliminary motion phase of interference 104,821, Imler filed a preliminary motion under 37 CFR § 1.633(i) to add claims 66 and 67 to its involved '143 application ('821, Paper 50).
10. Wang opposed the Imler preliminary motion to add claims 66 and 67 on the basis that, *inter alia*, claims 66 and 67 are not patentable to Imler over certain prior art ('821, Paper 73).
11. Imler's preliminary motion to add claims 66 and 67 was granted ('821, Paper 116 at 42).
12. In granting Imler's preliminary motion the panel noted that ('821, Paper 116 at 25):

Wang's argument that proposed Imler claims 66 and 67 are unpatentable over the prior art fails because the relied upon prior art is not in evidence.

13. In reply to Wang's opposition to Imler's preliminary motion to add claims 66 and 67 to the '143 application, Imler pointed out that Wang had not put into evidence the relied upon prior art ('821, Paper 92 at 2, n.1).
14. Nonetheless, it does not appear from a review of the '821 record that Wang made any attempt during the pendency of the '821 interference to supplement the record by placing into evidence the relied upon prior art.
15. The '821 record indicates that Wang did not request reconsideration of the decision granting the Imler preliminary motion seeking to add claims 66 and 67 to the '143 application.
16. Claims 66 and 67 that were added to the '143 application during the '821 interference are the same claims 66 and 67 that are involved in the present interference.

The motions of the present interference

17. Because it was determined that a preliminary motion period as to Imler's '143 claims was de facto provided in the '821 interference, Wang was not authorized to file a preliminary motion under 37 CFR § 1.633(a) attacking the patentability of Imler's '143 claims (Paper 32 at 10-11).
18. However, since Imler's '007 claims were not involved in the '821 interference, Wang was authorized to file a preliminary motion under 37 CFR § 1.633(a) seeking judgment that Imler's involved '007 claims are not patentable

to Imler (Paper 32 at 14).³

19. Prior to its filing the authorized preliminary motion, the time came due for Wang to file its case-in-chief on the issue of priority (Paper 22 at 3).
20. However, Wang did not timely file its case-in-chief.⁴
21. Imler was authorized to file a miscellaneous motion seeking judgment against Wang on the basis that Wang had conceded priority (Paper 38 at 2).
22. Imler filed its miscellaneous motion 1 on 9 January 2004 (Paper 39).
23. In addition to seeking immediate judgment against Wang, Imler requested that Wang not be permitted to file any preliminary motion under 37 CFR § 1.633(a) attacking the patentability of the '007 corresponding claims (Paper 39 at 10, n. 5).
24. Wang filed an opposition to the Imler miscellaneous motion (Paper 46) and Imler replied (Paper 49).
25. On 16 January 2004, Wang filed its preliminary motion 1 under 37 CFR § 1.633(a) seeking judgment that Imler's '007 corresponding claims are unpatentable (Paper 40).

³ Imler requested reconsideration of the portion of the decision allowing Wang to attack the patentability of the '007 claims. (Paper 38) However, the decision was not modified. (Paper 41 at 7).

⁴ During a conference call on 22 December 2003, Wang confirmed that it had not filed its priority case-in-chief within the time set (Paper 37 at 1).

26. Imler opposed Wang preliminary motion 1 (Paper 45) and Wang replied (Paper 50).
27. Thereafter, Imler requested authorization to file a preliminary motion under 37 CFR § 1.633(i) in response to Wang's preliminary motion 1 (Paper 52 at 2).
28. In an order entered 24 March 2004, Imler's request to file the responsive motion was denied. In particular, the order stated (Paper 52 at 2):

Imler's request to file a preliminary motion under 37 CFR § 1.633(i) is DENIED. If Wang preliminary motion 1 is granted, then Imler may present new or amended claims when it returns to *ex parte* prosecution before the examiner.

The cancelling of the '007 claims

29. Oral argument was set in the interference for 19 April 2004 (Paper 51).
30. During a series of conference calls, Imler sought and was given authorization to file an amendment cancelling all the '007 claims that correspond to the count (Paper 59 at 3).
31. In view of Imler's amendment cancelling the '007 claims (Paper 58), oral argument was cancelled (Paper 59).
32. During one of the conference calls, Wang indicated that it did not oppose Imler being authorized to cancel the '007 corresponding claims and to pursue patentable claims during *ex parte* prosecution. However, Wang did not agree that a judgment of priority against Wang was appropriate.

33. In a subsequent conference call, Wang argued that judgment on priority should be entered against Imler's '007 application under 37 CFR § 1.662. Wang indicated that it may be appropriate to enter judgment on priority against Imler's '007 application and Wang.

The prior art

34. Imler '143 claims 66 and 67 are as follows:

66. An adenovirus which is defective for replication, and which is derived from a natural adenovirus in that it lacks at least part of the E1A, E1B, or both regions, and at least a part of the E4 region, so that it is defective for the E1 and E4 functions and can be prepared by passage in a cell line providing the E1 and E4 functions *in trans*, and which comprises an exogenous nucleotide sequence.

67. A recombinant adenovirus comprising an adenovirus genome having a foreign gene and a promoter for expressing said foreign gene, wherein the function of an adenoviral E1 gene and an adenoviral E4 gene are completely deleted by removing a part or all of said E1 gene and said E4 gene.

35. In its preliminary motion 1 Wang relied upon the following references.

- (a) Berkner, *Biotechniques*, 6:616-629 (1988) (Exh. 2011) ("Berkner I"),
- (b) Berkner, *Current Topics in Microbiology and Immunology*, 158:39-66 (1992) (Exh. 2012) ("Berkner II"),
- (c) Bridge et al., *Journal of Virology* 63:631-638 (1989) (Exh. 2021) ("Bridge I"),
- (d) Bridge et al., *Virology* 174:345-369 (1990) (Exh. 2026) ("Bridge II").

36. In its preliminary motion 1 Wang requests that, in addition to holding that the '007 claims are unpatentable to Imler, we make a recommendation to the examiner under 37 CFR § 1.659(a) as to Imler's '143 claims.
37. Both Berkner I and Berkner II appear to be review articles discussing the expression of heterologous genes in adenoviral vectors.
38. Berkner I states that "[g]eneration of a transformed cell line (293) which encodes the E1 region of the Ad5 genome (44) has been invaluable in facilitating the isolation of Ad^[5] mutants by complementation" (Exh. 2011 at 616).
39. According to Berkner I (Exh. 2011 at 619-620):
- ...it is now theoretically possible to substitute up to 7.5 Kb of heterologous sequences into Ad, generating a viable, conditional, helper-independent Ad vector. This is due to the large genome size, to deletions which can be made in the dispensable E3 region and in E1 using complementation on 293 cells, and to the fact that Ad recombinants of 106 mu (i.e. 38 Kb) in size can still be packaged into virions. Potential deletions in the E4 regions, as mentioned above, may permit even larger gene inserts.
40. Berkner I describes adenoviral vectors "developed so far" as having "cassettes expressing foreign genes substituted for the E1 or E3 region and propagated in 293 cells". (Exh. 2011 at 621).
41. Berkner II indicates that substitution of either the E1 or E4 region of the adenoviral genome with heterologous sequences results in recombinants that may be propagated using complementing cell lines. (Exh. 2012 at 47).

⁵ Adenovirus.

42. Berkner II states that (Exh. 2012 at 47):

Generation of helper-independent Ad recombinants can be accomplished by insertion of heterologous sequences into several different regions of the Ad genome....Substitution of the E1 or E4 regions produces conditional recombinants which can be propagated in complementing cell lines.

and that (Exh. 2012 at 40):

The creation of a human cell line (293) that contains and expresses most of the E1a and E1b regions [citation omitted] has been invaluable both in the genetic analysis of these regions and in the complementation of Ad recombinants with heterologous sequences substituted for E1.

and that (Exh. 2012 at 46):

The Ad genome is large (~ 36 kb) and current helper-independent vectors have the capacity to accept up to approximately 7.5. kb of foreign DNA. This results from the ability to package genomes of up to 106 mu (i.e., 38 kb) [and] from the availability of cell lines that express and thus complement the E1 or E4 regions...

and that (Exh. 2012 at 46):

Another limitation [on the use of adenoviral vectors] is that wild-type (wt) Ad infection ultimately kills the host cell, thereby limiting the time scale for protein production.

43. Berkner II describes methods for generating adenovirus recombinants. (Exh. 2012 at 47-50).
44. Berkner II notes that "[f]oreign genes have...been inserted into the Ad genome as part of a self-sufficient expression cassette that includes a promoter". (Exh. 2012 at 47).

45. Berkner II does not specifically describe an adenovirus mutant having deletions in both the E1 and E4 regions of the adenovirus genome.
46. Bridge II reports the construction and testing of mutant human type 5 adenoviruses having deletions in the E1b and E4 regions. (Exh. 2026, Fig. 1, at 347).
47. According to Bridge II, at least one of the mutants, i.e., H5d/1016, is defective for DNA replication. (2026 at 349 (Table 2) and 352).
48. According to Bridge II, it appears that the "joint disruption [in H5d/1016] of the 116R and 496R proteins [i.e., the products of E4 open reading frame 3 (E4 ORF3) and of E1b, respectively] is important in conferring the defect in DNA replication". (Exh. 2026 at 352).
49. Bridge II reports that the H5d/1016 mutant was propagated using the 293 cell line. (Exh. 2026 at 347).
50. Bridge II reports that other mutants were propagated using "the E4 complementing cell line W162". (Exh. 2026 at 347).

IV. Discussion

We have before us a situation where junior party has failed to file its case-in-chief on priority. Ordinarily it may be appropriate to enter judgment against junior party forthwith. However, because a somewhat unusual schedule was established in the interference, we have before us an undecided preliminary motion for judgment against

senior party's corresponding '007 claims as well as an amendment from senior party cancelling the corresponding '007 claims.

Patentability

a. The '143 claims

Wang was given a full opportunity to attack the patentability of the '143 claims that correspond to the count, i.e., claims 66 and 67, during the '821 interference. (FF⁶ 10). Wang's attack failed. (FF 11). Based on the same reasons that Imler's claims were not shown to be unpatentable to it in the '821 interference (FF 12), a determination has been made that Imler's claims have not been shown to be unpatentable to it in the present interference.

b. The '007 claims

Since Wang was not given an opportunity to attack the patentability of the '007 claims during the '821 interference, Wang was authorized to file a preliminary motion under 37 CFR § 1.633(a) attacking the patentability of the '007 corresponding claims during the present interference. (FF 17). Wang filed such a preliminary motion. (FF 25).

When a party files a preliminary motion under 37 CFR § 1.633(a), it may be appropriate to authorize the party's opponent to file a preliminary motion under 37 CFR § 1.633(i). Imler requested authorization to file a § 1.633(i) preliminary motion after

⁶ Finding of fact.

briefing on Wang preliminary motion 1 was complete. (FF 27).⁷ Imler's request was denied. However, the order stated that, should Wang's preliminary motion 1 be granted, Imler could pursue new or amended claims before the examiner upon the resumption of *ex parte* prosecution. (FF 28).

Thereafter, Imler sought and was given authorization to file an amendment cancelling its '007 claims that correspond to the count. (FF 30). We take Imler's cancellation of its '007 corresponding claims as concession of unpatentability of the cancelled claims over the prior art cited in Wang preliminary motion 1. (FF 35). Accordingly, entering judgment against Imler's '007 claims that correspond to the count is appropriate. The judgment is with prejudice to Imler in that Imler is not entitled to a patent containing any of the cancelled claims. Imler's cancellation does not unfairly prejudice Imler in that Imler is entitled to pursue claims before the examiner that are patentable over the prior art cited in Wang's preliminary motion 1.⁸ Thus, Imler is in no worse a position than it would have been had we authorized it to file a responsive preliminary motion under 37 CFR § 1.633(i).

⁷ It is not clear on the record before us whether Imler requested authorization to file a § 1.633(i) preliminary motion at any earlier time in the interference.

⁸ As noted by Imler, it is under an affirmative duty to disclose the prior art cited in Wang's preliminary motion 1 upon the resumption of *ex parte* prosecution. (Paper 39 at 8).

Wang argued that judgment on priority should be entered against Imler's '007 application under 37 CFR §1.662(a). (FF 33). 37 CFR §1.662(a) states as follows:

A party may, at any time during an interference, request and agree to entry of an adverse judgment. The filing by a party of a written disclaimer of the invention defined by a count, concession of priority or unpatentability of the subject matter of a count, abandonment of the invention defined by a count, or abandonment of the contest as to a count will be treated as a request for entry of an adverse judgment against the applicant or patentee as to all claims which correspond to the count. Abandonment of an application, other than an application for reissue having a claim of the patent sought to be reissued involved in the interference, will be treated as a request for entry of an adverse judgment against the applicant as to all claims corresponding to all counts. Upon the filing by a party of a request for entry of an adverse judgment, the Board may enter judgment against the party.

37 CFR § 1.662(a) does not appear to address the situation before us, i.e., where a party has cancelled only some of its claims that correspond to the count and where the party was not given an opportunity to present new or amended claims via a § 1.633(i) responsive preliminary motion. Thus, under the circumstances before us, we do not treat Imler's amendment cancelling its corresponding '007 claims as a request for adverse judgment under 37 CFR § 1.662(a).

Because Imler has cancelled its '007 claims that correspond to the count, Wang's preliminary motion 1 attacking the patentability of these claims is moot. Wang preliminary motion 1 is DISMISSED. Imler's miscellaneous motion 1 seeking immediate judgment against Wang prior to a decision on preliminary motion 1 is also DISMISSED as moot. Since Wang preliminary motion is dismissed as moot, we do not reach Wang

reply 1. Accordingly, the Imler motion to strike Wang's reply (Paper 56) is DISMISSED as moot.

Priority

Before Wang's preliminary motion 1 was filed the time came for Wang to file its case-in-chief on priority. Wang failed to file its priority case-in-chief. (FF 20).

Because Wang did not timely file a priority case-in-chief, it is appropriate to enter judgment against Wang as to priority. 37 CFR § 1.652.⁹

Rule 659 recommendation

37 CFR § 1.659(a) states the following:

Should the Board have knowledge of any ground for rejecting any application claim not involved in the judgment of the interference, it may include in its decision a recommended rejection of the claim. Upon resumption of *ex parte* prosecution of the application, the examiner shall be bound by the recommendation and shall enter and maintain the recommended rejection unless an amendment or showing of facts not previously of record is filed which, in the opinion of the examiner, overcomes the recommended rejection.

In view of prior art that was submitted by Wang in its preliminary motion 1 (copies attached) and in accordance with 37 CFR § 1.659(a) the following rejection is recommended:

⁹ As noted in the order entered 23 December 2003, "[n]o order to show cause is necessary in this situation because the positions of the parties are clear enough" (Paper 37 at 1-2).

Claims 66 and 67 of Imler's '143 application (FF 34) are rejected under 35 USC § 103(a) as being obvious in view of Berkner II (FF 35 (b)) and Bridge II (FF 35(d)).

Berkner II describes the use of adenoviruses as expression vectors. Berkner II states that "[g]eneration of helper-independent Ad recombinants can be accomplished by insertion of heterologous sequences into several different regions of the Ad genome....Substitution of the E1 or E4 regions produces conditional recombinants which can be propagated in complementing cell lines". (FF 42). Berkner II describes methods for generating Ad recombinants. (FF 43). Berkner II notes that "[f]oreign genes have...been inserted into the Ad genome as part of a self-sufficient expression cassette that includes a promoter". (FF 44). Berkner II does not specifically describe an adenovirus mutant having deletions in both the E1 and E4 regions of the adenovirus genome. (FF 45).

Bridge II describes adenovirus mutants having deletions in a portion of both the E1b and E4 regions of the viral genome. (FF 46). At least one of these mutants, i.e., that mutant designated H5d/1016, is said to be defective for DNA replication. (FF 47). H5d/1016 is said to have been propagated in the 293 cell line (FF 49), a cell line that Berkner II describes as containing and expressing most of the E1a and E1b regions of the Ad5 genome. (FF 42).

It would have been obvious to one having ordinary skill in the art at the time of the invention to select an adenovirus mutant such as H5d/1016 to use as an expression

vector for heterologous genetic material. As noted in Berkner II, infection by wild type adenovirus will ultimately kill the host cell. (FF 50). Thus, one skilled in the art would have been motivated to use a mutant, such as H5d/1016, that is unable to replicate on its own.

As the deletions present in H5d/1016 render the mutant replication defective, it follows that H5d/1016 is defective for at least a portion of the functions of E1b and E4. In particular, Bridge II states that "the joint disruption of the 116R and 496R proteins [in H5d/1016] is important in conferring the defect in DNA replication". (FF 48). It also follows that H5d/1016 could be propagated in a cell line that provides both E1b and E4 functions.¹⁰

As we have noted the H5d/1016 mutant was propagated in the 293 cell line (FF 49) which only complements for E1 (FF 42). This indicates that the 116R protein encoded by E4 ORF 3 is not necessary for DNA replication of the H5d/1016 mutant. The data presented in Bridge II indicate that the virus is able to replicate if either E4 ORF 6 or ORF 3 is present. (Table II at 349). H5d/1016 does not contain a deletion of E4 ORF 6 and thus can replicate in the 293 cell line. Moreover, neither claim 66 nor claim 67 requires deletion in E4 such that the E4 deletions alone would result in a virus

¹⁰ The prior art before us describes a cell line (293) that is said to complement for E1 and a cell line that is said to complement for E4 (W162). (FF 42 and 50). However, since neither claim 66 nor claim 67 requires a cell line (claim 66 requires that the defective virus "can be prepared by passage in a cell line providing the E1 and E4 functions *in trans*"), we need not decide if a cell line complementing for both E1 and E4 would have been obvious.

that is replication defective. In other words, neither claim requires a "lethal" E4 deletion.

We further recommend that the examiner reject claims 66 and 67 of the '143 application under any other appropriate basis upon the resumption of *ex parte* examination of the '143 application, including rejecting the claims in view of Berkner I, Berkner II, Bridge I, Bridge II in combination with any other prior art within the examiner's knowledge.

V. Order

Upon consideration of the record and for reasons given, it is

ORDERED that Imler's proposed amendment (Paper 58, copy attached) shall be entered into the application file of application 09/739,007;

FURTHER ORDERED that Wang preliminary motion 1 (Paper 40), Imler miscellaneous motion 1 (Paper 39), and Imler's motion to strike (Paper 56) are each DISMISSED as moot;

FURTHER ORDERED that judgment on priority is entered against junior party QING WANG, MITCHELL H. FINER and XIAO-CHI JIA;

FURTHER ORDERED that junior party QING WANG, MITCHELL H. FINER and XIAO-CHI JIA is not entitled to a patent containing claims 37, 38, 46, 47, 52, 54, and 56 of its 08/333,680 application which correspond to Count 1 (Paper 14 at 8), the sole count in the interference;


FURTHER ORDERED that senior party JEAN-LUC IMLER, MAJID MEHTALI and ANDREA PAVIRANI is not entitled to a patent containing claims 73-77, 80-88, 91, and 92 of application 09/739,007;

FURTHER ORDERED that upon resumption of *ex parte* prosecution, it is recommended in accordance with 37 CFR §1.659(a) that the examiner reject claims 66 and 67 of Imler's 09/218,143 application for reasons set forth above;

FURTHER ORDERED that if there is a settlement agreement, the parties' attention is directed to 35 USC § 135(c); and

0452
RICHARD TORCZON
Administrative Patent Judge

-) BOARD OF PATENT
-) APPEALS AND
-) INTERFERENCES


SALLY GARDNER LANE
Administrative Patent Judge

Exh. 2011, Exh. 2012, Exh. 2021, and Exh. 2026

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